

Draft

PROPOSED CLAIMS

Claim 47. (Currently Amended) ~~Method of treatment of a patient suffering from a disease~~ A method for treating a patient suffering from a disease that is known to be treatable with a protein or polypeptide that is known to be effective in the treatment of the disease, comprising administering to the said patient a pharmaceutical composition for parenteral administration comprising a therapeutically effective amount of the protein or polypeptide ~~effective in the treatment of the disease and~~ non-covalently bound to a colloidal particle[[s]], the said colloidal particle[[s]] comprising approximately 1-20 mole percent of an amphipathic lipid derivatized with a biocompatible hydrophilic polymer,

wherein the said protein or polypeptide is selected from the group consisting of:

- (a) Factor VIIa, granulocyte colony-stimulating factor (G-CSF), granulocyte macrophage colony-stimulating factor (GM-CSF), interferon γ , glucagon-like peptide 1 (GLP-1) and Copaxone; and ~~proteins or polypeptides capable of externally binding said colloidal particles;~~
- ~~(b) proteins or polypeptides capable of binding polymers of the polyalkylether, polylactic and polyglycolic acid families; and~~
- ~~(c)~~(b) proteins or polypeptides that include a consensus sequence of S/T-X-L/I/V-I/V/Q/S-S/T-X-X-E, where X may be any amino acid, and S, T, L, I, V, E and Q have their standard meanings;

wherein the said protein or polypeptide is not Factor VIII (FVIII), and

wherein the said protein or polypeptide is not encapsulated in the said colloidal particle.

Claim 53. (New) A method for treating a patient suffering from a disease that is known to be treatable with a protein or polypeptide that is known to be effective in the treatment of the disease, comprising administering to the patient a pharmaceutical composition for parenteral administration comprising a therapeutically effective amount of the protein or polypeptide non-covalently bound to a colloidal particle, the colloidal particle comprising approximately 1-20 mole percent of an amphipathic lipid derivatized with a biocompatible hydrophilic polymer,

wherein the protein or polypeptide is selected from the group consisting of Factor VIIa, granulocyte colony-stimulating factor (G-CSF), granulocyte macrophage colony-stimulating factor (GM-CSF), interferon γ , glucagon-like peptide 1 (GLP-1) and Copaxone, and

wherein the protein or polypeptide is not encapsulated in the colloidal particle.

Claim 54. (New) A method for extending the half-life of a protein or polypeptide in vivo, comprising administering to a patient a pharmaceutical composition for parenteral administration comprising a therapeutically effective amount of the protein or polypeptide non-covalently bound to a colloidal particle, the colloidal particle comprising approximately 1-20 mole percent of an amphipathic lipid derivatized with a biocompatible hydrophilic polymer,

wherein the protein or polypeptide is selected from the group consisting of:

- (a) Factor VIIa, granulocyte colony-stimulating factor (G-CSF), granulocyte macrophage colony-stimulating factor (GM-CSF), interferon γ , glucagon-*like* peptide 1 (GLP-1) and Copaxone; and
- (b) proteins or polypeptides that include a consensus sequence of S/T-X-L/I/V-I/V/Q/S-S/T-X-X-E, where X may be any amino acid, and S, T, L, I, V, E and Q have their standard meanings;

wherein the protein or polypeptide is not Factor VIII (FVIII), and

wherein the protein or polypeptide is not encapsulated in the colloidal particle.

Claim 55. (New) A method for extending the half-life of a protein or polypeptide in vivo, comprising administering to a patient a pharmaceutical composition for parenteral administration comprising a therapeutically effective amount of the protein or polypeptide non-covalently bound to a colloidal particle, the colloidal

particle comprising approximately 1-20 mole percent of an amphipathic lipid derivatized with a biocompatible hydrophilic polymer,

wherein the protein or polypeptide is selected from the group consisting of Factor VIIa, granulocyte colony-stimulating factor (G-CSF), granulocyte macrophage colony-stimulating factor (GM-CSF), interferon γ , glucagon-like peptide 1 (GLP-1) and Copaxone, and

wherein the protein or polypeptide is not encapsulated in the colloidal particle.